IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

WANDA RUTH COUSINS, Plaintiff, VS. WYETH PHARMACEUTCAL, INC., d/b/a WYETH, Individually and as Successor-in-Interest to A.H. ROBINS, INC. and AMERICAN HOME PRODUCTS CORPORATION, *et al.*, Defendants.	§ § § § § § § § § § §	CIVIL ACTION NO. 3:08-CV-310-N

PLAINTIFF'S FIRST AMENDED ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE GODBEY:

NOW COMES WANDA RUTH COUSINS, hereinafter referred to as Plaintiff, complaining of Wyeth Pharmaceutical, Inc. d/b/a Wyeth, Individually and as Successor-In-Interest to A.H. Robins, Inc. and American Home Products Corporation; Schwarz Pharma, Inc.; Teva Pharmaceuticals, USA, Inc., a Delaware Corporation; and Teva Pharmaceuticals, LTD., an Israeli Corporation; hereinafter referred to as "Defendants," and for cause of action would respectfully show this Court and Jury the following:

I.
PARTIES AND JURISDICTION

1.01 Plaintiff WANDA RUTH COUSINS is an individual and is now, and at all relevant times mentioned in this Complaint was, a resident of the City of Ferris, Ellis County, State of Texas.

1.02 Plaintiff is able to bring action in this Court against foreign corporation Defendants, WYETH, INC. d/b/a WYETH, Individually and as Successor-In-Interest to A.H. ROBINS, INC., AMERICAN HOME PRODUCTS CORPORATION; SCHWARTZ PHARMA, INC.; TEVA

PHARMACEUTICALS, USA, INC., a Delaware corporation;; and TEVA PHARMACEUTICALS, LTD., an Israeli Corporation.

1.03 Defendant WYETH PHARMACEUTICALS, INC., (hereinafter WYETH**)** was and is a Delaware corporation with its principal place of business at 500 Arcola Drive, Collegeville, Pennsylvania. At all times material hereto, WYETH was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor-in-interest, or other related entities, metoclopramide tablets in the State of Texas and in interstate commerce. Defendant WYETH has already answered and appeared herein.

1.04 Defendant WYETH, INC. was and is a Delaware corporation headquartered and with its principal place of business at 5 Giralda Farms, Madison, New Jersey and is the successor-in-interest to A.H. Robins Company, Inc., a Virginia corporation. At all times material hereto**,** WYETH, INC. was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor-in-interest, or other related entities, metoclopramide tablets in the State of Texas and in interstate commerce. Defendant WYETH, INC. has already answered and appeared herein.

1.05 Defendant SCHWARZ PHARMA, INC. (hereinafter SCHWARZ) is a Delaware corporation duly qualified to do business in the State of Texas with its principal place of business in Mequon, Wisconsin. At all times material hereto, Defendant SCHWARZ was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor-in-interest, or other related entities, metoclopramide tablets in the State of Texas and in interstate commerce. Defendant SCHWARZ has already answered and appeared herein.

1.06 Defendant TEVA PHARMACEUTICALS, USA, INC. is a Delaware corporation headquartered and with its principal place of business in Delaware and Pennsylvania and is a subsidiary or division of TEVA PHARMACEUTICALS, LTD**,** an Israeli corporation and is hereinafter referred to as TEVA. At all times material hereto, TEVA was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, metoclopramide tablets in the State of Texas and in interstate commerce. The authorized agent for TEVA is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 1801.

1.07 All Defendants, identified *supra*, inclusive, and each of them, hereinafter may be referred to collectively as "THE MANUFACTURING DEFENDANTS."

1.08 This case was originally filed in District Court in the State of Texas and was removed by the Defendants. Currently, this Court maintains jurisdiction on the basis of diversity, 28 U.S.C. § 1332, in that the matter in controversy exceeds $75,000.00 exclusive of interest and costs and is between citizens of different states.

1.09 Beginning in approximately May of 1983, and continuing through approximately January of 2005, Plaintiff was treated for diabetic gastroparesis and/or for the treatment of gastroesophageal reflux disease (GERD) and/or for the treatment of irritable bowel syndrome and/or other gastrointestinal disorders.

1.10 Plaintiff was prescribed and ingested the pharmaceutical drug Reglan and/or metoclopramide during that course of treatment. Those prescriptions were written in Texas, filled in Texas and the drug was consumed in Texas – all of within the Northern District of Texas Federal District Court.

1.11 Plaintiff was diagnosed with Tardive Dyskinesia, a severe disfiguring condition. Plaintiff's tardive dyskinesia is permanent and was caused by the use of the aforementioned drugs. Reglan and/or metoclopramide pharmaceutical drugs are designed, manufactured, marketed and sold by MANUFACTURING DEFENDANTS.

1.12 At all relevant times, MANUFACTURING DEFENDANTS were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

1.13 At all times relevant hereto**,** MANUFACTURING DEFENDANTS were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising the pharmaceutical drugs known and/or branded as Reglan and/or the generic equivalent, metoclopramide HCl and/or metoclopramide, in the State of Texas and in interstate commerce.

1.14 At all relevant times, MANUFACTURING DEFENDANTS did manufacture, create, design, assemble, test, label, sterilize, package, distribute, promote, supply, market, sell, advertise, and/or otherwise distribute in the State of Texas and in interstate commerce Reglan and/or metoclopramide tablets.

1.15 At all relevant times, MANUFACTURING DEFENDANTS sold, delivered and/or distributed such products for ultimate sale and/or use interstate commerce within the United States and the State of Texas by consumers, including Plaintiff.

II.
FACTS

2.01 This case involves the "prokinetic" drug branded as "Reglan" and/or generic metoclopramide and/or metoclopramide HCl (hereinafter referred to as "metoclopramide").

2.02 The terms "Reglan" and/or metoclopramide and/or metoclopramide HCl are frequently used to refer to all metoclopramide products, including the name brand product and its generic equivalents.

2.03 Metoclopramide is a drug that helps control gastroesophageal reflux disease (GERD) and/or for the treatment of irritable bowel syndrome and/or other gastrointestinal disorders by blocking dopamine receptors in the brain and throughout the body, thus enhancing movement or contractions of the esophagus, stomach and intestines.

2.04 The sole active ingredient contained in Reglan and/or metoclopramide tablets is the drug metoclopramide HCl (also known as metoclopramide).

2.05 The terms "Reglan" and "metoclopramide" are both frequently employed to refer to all metoclopramide products, including the name brand product and its generic equivalents.

2.06 MANUFACTURING DEFENDANTS did market and/or distribute these drugs and encouraged the use of these drugs, misrepresented the effectiveness of the drugs and concealed the dangerous side effects of Reglan and/or metoclopramide.

2.07 The drugs Reglan and/or metoclopramide were widely advertised by MANUFACTURING DEFENDANTS as a safe and effective treatment of gastroesophageal reflux disease (GERD) and/or for the treatment of irritable bowel syndrome and/or other gastrointestinal disorders.

2.08 MANUFACTURING DEFENDANTS' strategy was to aggressively market and sell the aforementioned drugs by misleading consumers, pharmacists, and physicians about the drugs and/or to purposefully downplay and understate the dangers and potential dangers of the aforementioned drugs to physicians and the public citizenry.

2.09 MANUFACTURING DEFENDANTS failed to protect or adequately warn users about the serious dangers, about which MANUFACTURING DEFENDANTS knew or should have known, that would result from the use of Reglan and/or metoclopramide.

2.10 A. H. ROBINS first obtained approval by the Food and Drug Administration to market and distribute Reglan in approximately 1983.

2.11 At all relevant times up to December 27, 2001, WYETH, predecessor-in-interest of A.H. ROBINS, marketed and manufactured and/or distributed, through its WYETH-Ayerst Laboratories Division in St. Davids, Pennsylvania., a certain prescription drug product known and/or branded as Reglan.

2.12 On December 27, 2001, Defendant SCHWARZ purchased the rights and liabilities associated with Reglan tablets and Reglan syrup from Defendants, WYETH and/or WYETH, INC**.,** pursuant to an Asset Purchase Agreement executed on that date which obligated it to be responsible for claims relating to or arising out of the ingestion or use of Reglan from and after March 31, 2002, subject to a right to indemnification by Defendants WYETH and/or WYETH, INC**.,** up to an amount not presently known by this Plaintiff.

2.13 From December 27, 2001, on, Reglan has been marketed and manufactured and/or distributed by Defendant SCHWARZ.

2.14 The term "Reglan" is the brand name for the drug product manufactured and/or distributed and marketed by Defendant WYETH, the predecessor-in-interest of A.H. Robins, and then subsequently, Defendant SCHWARZ.

2.15 The generic metoclopramide products, marketed by some and/or all of MANUFACTURING DEFENDANTS contain the same active ingredient as the drug known and/or

branded as Reglan, and are equivalent to Reglan in dosage, strength, and all other therapeutically material respects, including potentially beneficial effects and side effects.

2.16 All wholesale shipments of the Reglan and/or metoclopramide products, and all samples of such products, are accompanied by "package inserts," as required by federal law for all prescription drug products. The package inserts contain information about the pharmaceutical drug, including the drug's active and inactive ingredients, pharmacokinetics, chemistry, warnings, and side effects.

2.17 The verbatim content of the package insert, for name brand prescription drug products, are typically published, at the instance of the manufacturer, as a so-called "monograph" for the product, in the Physician's Desk Reference (PDR), an annual compilation of such monographs, supplemented periodically.

2.18 A monograph for any prescription drug product may be published in the PDR at the instance of its manufacturer, upon payment of a fee to the publisher.

2.19 The package insert for Reglan was developed by the A.H. Robins Company, and subsequently adopted by Defendant WYETH, and then, subsequently adopted by Defendant SCHWARZ, with revisions from time to time, subject to FDA approval and published upon payment of the applicable publication fees. Reglan monographs (PDR) have been published for every year, save for one.

2.20 The manufacturers of generic metoclopramide products adopted as the package inserts for their products, the verbatim content of the package insert for the pharmaceutical drug known and/or branded as Reglan, as revised from time to time, modified only to reflect therapeutically non-relevant differences among the products, such as color, shape, inactive ingredients, and source of manufacture.

2.21 Indicated uses for Reglan and/or metoclopramide products, as reflected in the text of their package inserts, and in the PDR monograph for Reglan, included "short term (4 to 12 weeks) therapy for symptomatic gastroesophageal reflux, and for diabetic gastroparesis."

2.22 The text of the Reglan and/or metoclopramide products package inserts further disclosed that exposure to Reglan and/or metoclopramide could cause extrapyramidal symptoms, including tardive dyskinesia and tardive dystonia, and other afflictions involving the central nervous system, and that the risk of developing tardive dyskinesia was "believed to increase with duration of treatment and total cumulative dose."

2.23 At all relevant times, the MANUFACTURING DEFENDANTS knew, or in the exercise of reasonable care toward patients who would be expected to ingest Reglan and/or metoclopramide products should have known, that:

a. Reglan and/or metoclopramide is a neuroleptic drug, classified as such (because of its effects on the central nervous system, specifically as a dopamine inhibitor) with other neuroleptic drugs, which are also classified as antipsychotic drugs (because of their use in treating schizophrenia), and which are commonly recognized, among internists, family and general practitioners, and gastroenterologists, as leading to a high incidence of tardive dyskinesia and related extrapyramidal symptoms when used for prolonged periods of *six months to a year or more*.

b. Some neuroleptic drugs, in the absence of data specific to the drug, are expected to lead to tardive dyskinesia in between an estimated 20% to 35% percent of patients who are exposed to the drug for prolonged periods.

c. The period for clinical trials for Reglan and/or metoclopramide tablets did not exceed three (3) months in duration of exposure to the patients.

d. The results of epidemiological studies, published in peer-reviewed scientific and medical literature, have consistently shown, for many years, a high prevalence of Tardive Dyskinesia and other extra pyramidal symptoms among Reglan and/or metoclopramide users, particularly those users exposed to the drug for prolonged periods.

e. These published epidemiological studies represent the best scientific evidence then available for evaluating the association between metoclopramide exposure and the prevalence or incidence of Tardive Dyskinesia and other extra pyramidal symptoms.

f. Gastroesophageal reflux and diabetic gastroparesis and/or other gastric disorders are typically and often experienced chronically or intermittently over sustained periods of time.

g. Physicians *commonly* prescribe Reglan and/or metoclopramide products, as treatment for gastroesophageal reflux and/or diabetic gastroparesis and other gastric disorders, for periods of six months to a year or more.

h. Defendant WYETH and A.H. ROBINS and the MANUFACTURING DEFENDANTS had actual knowledge, through their own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan and/or metoclopramide received it on doctor's prescriptions for 12 months or longer *rather* than twelve (12) weeks or less (the duration in the PDR).

2.24 The package inserts for Reglan and/or metoclopramide products, and the PDR monograph for Reglan and/or metoclopramide contained false and/or misleading statements and omitted information material to the foreseeable and ordinary contemplated uses of the products. These statements and omissions include:

a. The statement that the most common extra pyramidal symptom occurred in approximately 1 in 500 hundred patients using Reglan and/or metoclopramide. This statement is without scientific evidence to support the assertion.

b. The omission of any reference to epidemiological studies and other evidence suggesting that the prevalence of Tardive Dyskinesia among patients exposed to Reglan and/or metoclopramide for six months or longer is as much as *100 times* greater than 1 in 500.

c. The statement that use of Reglan and/or metoclopramide products for longer than 12 weeks "had not been evaluated" and therefore "cannot" be recommended. The statement misleadingly implies that the manufacturer has performed no evaluation of longer term use or that use for longer than twelve (12) weeks would be recommended if only formal evaluations or clinical studies for such periods had been performed.

d. The statement that the risk of tardive dyskinesia from exposure to Reglan and/or metoclopramide is "believed" to increase with duration of treatment and total cumulative dose. The statement misleadingly implies that the "belief" is not supported, or not strongly supported, by scientific evidence.

2.25 The omission of any statement that therapy with Reglan and/or metoclopramide should not extend beyond three (3) months, which implies, in context, that no scientific evidence suggests, or strongly suggests, that longer term use increases substantially the risks of overexposure.

2.26 Introducing Reglan and/or metoclopramide products into interstate commerce and to the U.S. market, the MANUFACTURING DEFENDANTS promoted, among physicians, the idea that long-term use of Reglan and/or metoclopramide products were both safe and effective.

2.27 The promotion of the long-term use of Reglan and/or metoclopramide included presentations by sales representatives (known as "detail men") emphasizing the drug's gastroenterological effects, in particular gastric emptying, at the expense of its extrapyramidal effects, including Tardive Dyskinesia; the sponsoring of talks and seminars with company-sponsored speakers, who would discuss the supposed benefits and safety of longer term use, ghost-authoring (also referred to as ghost-writing) literature and publications which were in fact company-sponsored, and dissemination of at least one junk science study calculated to "demonstrate" the safety of long-term Reglan and/or metoclopramide use, when in fact the MANUFACTURING DEFENDANTS knew otherwise.

2.28 MANUFACTURING DEFENDANTS, by affirmative misrepresentations and omissions, falsely and fraudulently created the image and impression that the drugs were safe drugs for the treatment gastroesophageal reflux disease (GERD) and/or for the treatment of irritable bowel syndrome and/or other gastrointestinal disorders gastric disorders, when in fact, the risk of severe side effects with these drugs far exceeded their potential benefits.

2.29 MANUFACTURING DEFENDANT**S** have never repudiated the substance of the aforementioned promotional activities or acted to neutralize its effects upon consumers, like Plaintiff, in the interstate commerce market and in the State of Texas.

2.30 In prescribing the Reglan and/or metoclopramide products for the Plaintiff as they did, the Plaintiff's physicians relied upon the information published in the package inserts and/or the PDR or otherwise disseminated by the MANUFACTURING DEFENDANTS, in particular the manufacturer/distributor of the name brand product known and/or branded as Reglan, and were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false, and/or otherwise inadequate information thus disseminated.

2.31 All else being equal, a physician's reliance on the information concerning the properties and effects of a drug or drug product, as contained in the package insert (or PDR monograph) for the drug product, or in other literature or statements disseminated by the manufacturer of the product, is foreseeable and reasonable, and equally foreseeable and reasonable as to the properties and effects of therapeutically equivalent generic drug products.

2.32 Plaintiff's physician could not know, and therefore did not inform Plaintiff of any side effects associated with long-term use of Reglan and/or metoclopramide, or that limitations on the duration of use for Reglan and/or metoclopramide products might be appropriate, or that use of Reglan and/or metoclopramide products for longer than twelve (12) weeks had "not been evaluated" by MANUFACTURING DEFENDANTS.

2.33 Plaintiff used the pharmaceutical drugs Reglan and/or metoclopramide without substantial change in condition in the products between the time of design, manufacture and sale of the products and the time Plaintiff used the products as directed.

2.34 The Plaintiff's use of Reglan and/or metoclopramide products, as prescribed, resulted in Plaintiff's overexposure to the drug Reglan and/or metoclopramide which caused Plaintiff to suffer serious, permanent and disabling injuries, including, but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems, specifically Tardive Dyskinesia, a severely disfiguring movement disorder, which is permanent.

2.35 Because of the injuries Plaintiff sustained from the ingestion of the prescription drug, Reglan and/or metoclopramide, the Plaintiff has experienced and will continue to experience medical and related expenses, Plaintiff's loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury, and other injuries and damages.

2.36 The Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the MANUFACTURING DEFENDANTS' dissemination to physicians of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Reglan and/or metoclopramide and the ingestion of Reglan and/or metoclopramide products, and as a foreseeable and proximate result of Plaintiff physicians' failure to ascertain and disclose to the Plaintiff accurate, non-misleading, and materially complete information concerning the drug and drug products' effects.

2.37 The Plaintiff took the metoclopramide products as prescribed continuously from December 7, 1983 through March 23, 2006.

III.
FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY

3.01 Plaintiff incorporates by reference all factual allegations made, *supra*, as if set out word for word in this paragraph.

3.02 The dangerous propensities of Reglan and/or metoclopramide products, as referenced above, were known or scientifically knowable, through appropriate research and testing, to the MANUFACTURING DEFENDANTS at the time said Defendants distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients. The dangerous propensities of the drugs were not known by consumers of the drugs, such as Plaintiff.

3.03 The Reglan and/or metoclopramide products, as distributed by the MANUFACTURING DEFENDANT**S**, were defective and unreasonably dangerous inasmuch as they were not accompanied by warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in

particular the common, foreseeable, and intended use of the products for long term Reglan and/or metoclopramide therapy.

3.04 Prior to the manufacturing, sale and distribution of said drug products, MANUFACTURING DEFENDANTS, and each of them, knew that said drug products were in a defective condition as previously described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries.

3.05 MANUFACTURING DEFENDANTS, and each of them, through their officers, directors and managing agents, had prior notice and knowledge from several sources, prior to the date of dispensing of said drug products to Plaintiff, that the drugs presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such said consumers of said drugs were unreasonably subjected to risk of injury or death from the consumption of said drugs.

3.06 Despite such knowledge, MANUFACTURING DEFENDANTS, and each of them, acting through their officers, directors and managing agents, for the purpose of enhancing MANUFACTURING DEFENDANTS' profits, knowingly and deliberately failed to warn the public, including Plaintiff, of the extreme risk of physical injury occasioned by said defects inherent in said drugs. MANUFACTURING DEFENDANTS intentionally proceeded with the manufacturing, the sale and distribution, and marketing of the drugs with knowledge that consumers would be exposed to serious danger in order to advance MANUFACTURING DEFENDANTS' own pecuniary interest.

3.07 The Reglan and/or metoclopramide products, as distributed by the MANUFACTURING DEFENDANTS, were defective and unreasonably dangerous inasmuch as they were not accompanied by warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in

particular the common, foreseeable, and intended use of the products for long term Reglan and/or metoclopramide therapy.

3.08 As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested, as prescribed, Reglan and/or metoclopramide, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by MANUFACTURING DEFENDANTS through third parties or related entities.

IV.
SECOND CAUSE OF ACTION
NEGLIGENCE

4.01 Plaintiff incorporates by reference all factual allegations, *supra*, as if set out word for word in this paragraph.

4.02 As manufacturers of prescription drug products, specifically Reglan and/or metoclopramide products, the MANUFACTURING DEFENDANTS owed a duty toward foreseeable users of Reglan and/or metoclopramide products, including the Plaintiff, to exercise reasonable care to ensure that the Reglan and/or metoclopramide products they manufactured and/or distributed were reasonably safe for their ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks inherent in such use.

4.03 Each of the MANUFACTURING DEFENDANTS breached their duty, including the duty to assure that their products did not cause users to suffer from foreseeable unreasonably dangerous side effects and serious health problems, to members of the public who were expected to use their Reglan and/or metoclopramide products, including the Plaintiff, by failing to exercise

reasonable care in testing the products for their effects in ordinary and foreseeable uses, including long term use, and in disseminating to physicians information concerning the effects of the product which was accurate, not misleading, and otherwise adequate to enable to physicians to make informed choices concerning the reasonably safe use of the products.

4.04 MANUFACTURING DEFENDANTS failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the drugs into the stream of interstate commerce in that MANUFACTURING DEFENDANTS knew or should have known that the drugs created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

4.05 The dangerous propensities of Reglan and/or metoclopramide products, as referenced above, were known or scientifically knowable, through appropriate research and testing, to the MANUFACTURING DEFENDANTS at the time they distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients. The dangerous propensities of the drugs were also not known by consumers, such as Plaintiff.

4.06 As manufacturers of prescription drug products, specifically Reglan and/or metoclopramide products, the MANUFACTURING DEFENDANTS owed a duty toward foreseeable users of Reglan and/or metoclopramide products, including the Plaintiff, to exercise reasonable care to ensure that the Reglan and/or metoclopramide products they manufactured and/or distributed were reasonably safe for their ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks inherent in such use.

4.07 Each of the MANUFACTURING DEFENDANTS breached their duty towards members of the public who were expected to use their Reglan and/or metoclopramide products, including the Plaintiff, by failing to exercise reasonable care in testing the products for their effects in ordinary and foreseeable uses, including long term use, and in disseminating to physicians information concerning the effects of the product which was accurate, not misleading, and otherwise adequate to enable to physicians to make informed choices concerning the reasonably safe use of the products.

4.08 The information the MANUFACTURING DEFENDANTS disseminated to physicians concerning their Reglan and/or metoclopramide products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

4.09 As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested, as prescribed, Reglan and/or metoclopramide, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by MANUFACTURING DEFENDANTS through third parties or related entities.

V.
THIRD CAUSE OF ACTION
NEGLIGENCE *PER SE*

5.01 Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

5.02 As part of their duty to exercise reasonable care for the safety of the public, including the Plaintiff, who would be expected to use their products, the MANUFACTURING DEFENDANTS were obliged to follow both federal and applicable state laws and regulations

enacted and promulgated to protect the safety of such persons which make it unlawful to misbrand prescription drug products.

5.03 The package inserts (and other consistent labeling and advertising materials) for the Reglan and/or metoclopramide products failed to conform to the requirements of federal and state law, inasmuch as the package inserts and/or other labeling contained false, inaccurate, and/or misleading statements concerning the products' side effects and omitted information, including warnings and instructions for use, adequate to enable the use of the products in an ordinary, foreseeable, and intended manner that was reasonably safe, taking into account the potential benefits and potential risks entailed in such use.

5.04 In distributing the Reglan and/or metoclopramide products labeled in violation of these statutes and associated regulations, each of the MANUFACTURING DEFENDANTS was negligent *per se*, as a matter of law.

5.05 As a foreseeable and proximate result of the negligence *per se* breaches of the MANUFACTURING DEFENDANTS, specifically their violation of the above referenced statutes and regulations, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physicians, in reasonable reliance upon the information disseminated by the MANUFACTURING DEFENDANTS in violation of the law and regulations, prescribed for the Plaintiff the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and Plaintiff ingested, per those prescriptions, Reglan and/or metoclopramide products manufactured by these MANUFACTURING DEFENDANTS, leading to Plaintiff's toxic overexposure to Reglan and/or metoclopramide.

VI.
FOURTH CAUSE OF ACTION
FRAUD

6.01 Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

6.02 The MANUFACTURING DEFENDANTS disseminated the false information, as referenced above, to physicians and, indirectly, to their patients, knowing the information to be false or in conscious disregard of whether it was false or not false, with the intention to deceive the physicians, and indirectly their patients, and to induce the physicians to prescribe Reglan and/or metoclopramide products, and in particular to prescribe Reglan and/or metoclopramide products for prolonged periods of time.

6.03 As a foreseeable and proximate result of this knowing dissemination of knowingly and/or recklessly false information, as referenced above, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physicians, in reasonable reliance upon this false information disseminated by the MANUFACTURING DEFENDANTS, and believing the information to be true, prescribed for the Plaintiff the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and he ingested, per those prescriptions, Reglan and/or metoclopramide products, leading to Plaintiff's toxic overexposure to Reglan and/or metoclopramide.

VII.
FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(AS AGAINST WYETH, WYETH, INC. AND SCHWARZ PHARMA)

7.01 Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

7.02 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ

PHARMA owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan and/or metoclopramide, to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

7.03 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ PHARMA disseminated to physicians, through package inserts, the publication of a PDR monograph, and otherwise, information concerning the properties and effects of Reglan and/or metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

7.04 It is the public policy of the United States and of this state, as reflected in the Hatch-Waxman Act, the laws and regulations of the State of Texas, and any other applicable state, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

7.05 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ PHARMA, as prescription drug manufacturers and/or distributors, knew or ought to have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product**.**

7.06 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ PHARMA, as innovator prescription drug manufacturers and/or distributors, knew or ought to have realized that the manufacturers and/or distributors of generic products, as a custom, to either ensure or give the impression that the information contained in the package inserts accompanying their own

generic prescription drug products is accurate, complete, not misleading, and otherwise adequate, typically and simply copy verbatim, for those package inserts, the therapeutically relevant content of the package insert for the name brand prescription drug product, for which the generic products are therapeutic equivalents; and, further, that the manufacturers of the counterpart generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

7.07 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ PHARMA, knew or ought to have realized that physicians, to obtain basic information about the properties and effects of a drug or drug product that is available in both name brand and generic formulations, commonly and typically consult the information disseminated by the manufacturer/distributor of name brand product, in PDR monographs or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients, whether by brand name or generic name, and that the patients are likely to receive and ingest, per those prescriptions, one or more generic products that are therapeutically equivalent to the name brand product.

7.08 MANUFACTURING DEFENDANTS WYETH and SCHWARZ knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using Reglan and/or metoclopramide products, whether name brand or generic or either, and in writing prescriptions for either "Reglan" or "metoclopramide," would rely upon information disseminated to them by the manufacturer of the name brand drug product, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Reglan and/or metoclopramide products, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan and/or metoclopramide products.

7.09 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ knew or ought to have realized that patients receiving prescriptions for Reglan or generic Reglan and/or metoclopramide written in reliance upon information they disseminated as the manufacturer/distributor of Reglan, the name brand Reglan product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

7.10 MANUFACTURING DEFENDANTS, WYETH, WYETH, INC., AND SCHWARZ**,** and their predecessors-in-interest, failed to exercise reasonable care to ensure that the information they disseminated to physicians concerning the properties and effects of Reglan and/or metoclopramide and Reglan was accurate and not misleading, and as a result disseminated information to physicians that was negligently and materially inaccurate, misleading, and false.

7.11 As a proximate and foreseeable result of this negligence on the part of MANUFACTURING DEFENDANTS, WYETH, WYETH, INC. and SCHWARZ, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physicians, in reasonable reliance upon the negligently inaccurate, misleading, and false information disseminated by said Defendants, and their predecessors-in-interest, and believing the information to be true, prescribed for the Plaintiff the use of Reglan and/or metoclopramide for a prolonged and unwarranted period of time and Plaintiff ingested, per those prescriptions, Reglan and/or metoclopramide products, leading to Plaintiff's toxic overexposure to Reglan and/or metoclopramide.

VIII.
SIXTH CAUSE OF ACTION
FRAUD BY CONCEALMENT

8.01 Plaintiff incorporates by reference all factual allegations made herein above, as if set out word for word in this paragraph.

8.02 The MANUFACTURING DEFENDANTS, with the intention of deceiving physicians and their patients, and to induce physicians to prescribe, and their patients to ingest, Reglan and/or metoclopramide products for prolonged periods of time, informed physicians, through package inserts and otherwise, that exposure to Reglan and/or metoclopramide can lead to Tardive Dyskinesia and other ESP, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than twelve (12) weeks "cannot be recommended," but knowingly concealed from the physicians material facts bearing on the interpretation of those disclosures, including the fact that earlier false information, disseminated by A.H. ROBINS COMPANY, and representing long-term Reglan and/or metoclopramide therapy to be reasonably safe, was unscientific and false; that Reglan and/or metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other ESP with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs; that epidemiological studies have consistently confirmed this expectation; and that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis, and/or other gastric disorders with Reglan and/or metoclopramide products for longer than 12 weeks is unlikely to be reasonably safe.

8.03 The Plaintiff's physicians, in reasonable reliance upon the information disseminated by the MANUFACTURING DEFENDANTS, and without knowledge of the undisclosed and knowingly concealed facts, determined that the benefits of prolonged Reglan and/or metoclopramide

therapy outweighed the risks for their patient, the Plaintiff, and prescribed a prolonged course of therapy for her with Reglan and/or metoclopramide products.

8.04 As a proximate and foreseeable result of this knowing and fraudulent concealment of material facts on the part of the MANUFACTURING DEFENDANTS, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physicians, in reasonable reliance upon the information disseminated by the MANUFACTURING DEFENDANTS, and in ignorance of the facts concealed from them in those disseminations, prescribed for the Plaintiff the use of Reglan and/or metoclopramide for a prolonged and unwarranted period of time and Plaintiff ingested, per those prescriptions, Reglan and/or metoclopramide products, leading to Plaintiff's toxic overexposure to Reglan and/or metoclopramide.

IX.
SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

9.01 Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

9.02 The Reglan and/or therapeutically equivalent generic Reglan and/or metoclopramide products materially failed to conform to those representations which the several MANUFACTURING DEFENDANTS made, in package inserts and otherwise, concerning the properties and effects of the products which they manufactured and/or distributed and sold, and which the Plaintiff purchased and ingested in direct or indirect reliance upon these express representations. That failure constituted a material breach of express warranties made, directly or indirectly, to the Plaintiff, concerning the products thus sold to the Plaintiff. Plaintiff and/or

Plaintiff's physicians reasonably relied upon these representations in making the decision to prescribe and/or consume the drugs.

9.03 As a foreseeable and proximate result of these breaches of express warranties on the part of the MANUFACTURING DEFENDANTS, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff physicians, in reasonable reliance upon the express warranties, prescribed for the Plaintiff the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and Plaintiff purchased and ingested, per those prescriptions, Reglan and/or metoclopramide products manufactured by these MANUFACTURING DEFENDANTS, leading to Plaintiff's toxic overexposure to Reglan and/or metoclopramide.

9.04 The Plaintiff notified the MANUFACTURING DEFENDANTS of the breaches of express warranties as soon as the breaches were ascertained and made known to Plaintiff.

X.
EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

10.01 Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

10.02 Each of the MANUFACTURING DEFENDANTS severally and impliedly warranted the Reglan and/or metoclopramide products which they manufactured and/or distributed and sold, and which the Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the products were sold, including specifically long-term Reglan and/or metoclopramide therapy for the treatment of chronic and/or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders. Plaintiff and/or

Plaintiff's physicians reasonably relied upon these representations in deciding to prescribe and/or consume the drugs.

10.03 The MANUFACTURING DEFENDANTS breached their implied warranties of the Reglan and/or metoclopramide products sold to the Plaintiff, because these products were not of merchantable quality or fit for their common, ordinary, and intended use in long term therapy for the treatment of chronic and/or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders.

10.04 As a foreseeable and proximate result of these breaches of implied warranties on the part of the MANUFACTURING DEFENDANTS, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's' physicians, in reasonable reliance upon the implied warranties, prescribed for the Plaintiff the use of Reglan and/or metoclopramide products for a prolonged and unwarranted period of time and she purchased and ingested, per those prescriptions, Reglan and/or metoclopramide products manufactured by these MANUFACTURING DEFENDANTS**,** leading to Plaintiff's toxic overexposure to Reglan and/or metoclopramide.

10.05 The Plaintiff notified the MANUFACTURING DEFENDANTS of the breaches of implied warranties as soon as the breach was ascertained and made known to Plaintiff.

XI.
NINTH CAUSE OF ACTION
UNFAIR TRADE PRACTICES

11.01 Plaintiff incorporates by reference all factual allegations made hereinabove, as if set out word for word in this paragraph.

11.02 By reason of the conduct as alleged herein, MANUFACTURING DEFENDANTS violated the provisions of the applicable unfair trade practices statute by knowingly and intentionally

inducing Plaintiff to use the drugs through the use of false and/or misleading advertising, representations and statements. The products failed to perform as represented and advertised, and in fact were unsafe.

11.03 The MANUFACTURING DEFENDANTS induced the Plaintiff and Plaintiff's physicians, through the use of false and/or misleading advertising, representations, and statements, as described above, to use and/or prescribe Reglan and/or metoclopramide products which they manufactured and/or distributed and sold, all in violation of the Texas Deceptive Trade Practices Act, the False and Misleading Advertising Act, the Texas Prevention of Consumer Fraud Act and the Uniform Deceptive Trade Practices Act, and any other applicable laws or regulations of the State of Texas, which proscribes, among other things:

a. Engaging in unfair trade practices as defined in the statute by making false and misleading oral and written statements that have the capacity, tendency or effect of deceiving or misleading consumers;

b. Engaging in unfair trade practices as defined in the statute by making representations that their products had an approval, characteristic, ingredient, use or benefit which they did not have, including but not limited to statements concerning the health consequences of the use of drugs;

c. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceive or tend to deceive, including but not limited to, facts relating to the health consequences of the use of these drugs; and

d. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression and omission of material

facts with the intent that consumers rely upon the same in connection with the use and continued use of the drugs.

11.04 As a direct and proximate result of MANUFACTURING DEFENDANTS' statutory violations, Plaintiff used the drugs as prescribed, which Plaintiff would not have used had MANUFACTURING DEFENDANTS not issued false and/or misleading advertising, representations and statements.

11.05 By reason of such violations and pursuant to the laws and regulations of this State, Plaintiff is entitled to recover all of the monies paid for the products; to be compensated for the cost of medical care arising out of the use of the products; together with any and all other consequential damages recoverable under the law including, but not limited to, past medical expenses, past wage loss, past pain, suffering, disability and emotional distress.

11.06 In addition, Plaintiff is entitled to recover fees and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.

11.07 Defendants WYETH (including A.H. Robins Company, Inc., prior to its merger into WYETH, and as WYETH thereafter) and SCHWARZ have marketed Reglan to physicians in a manner calculated to increase sales of the drug and resultant profits to the drug companies at the expense of and in conscious disregard for the health and safety of those who, through over-prescription of the drug at excessive dosage and/or for excessive periods of time and/or for patients for whom safer effective alternative treatments existed, consequently develop tardive dyskinesia and other extrapyramidal symptoms (EPS).

XII.
PUNITIVE DAMAGES (AS AGAINST MANUFACTURING DEFENDANTS

12.01 Plaintiff incorporates by reference all factual allegations made herein above, as if set out word for word in this paragraph.

12.02 MANUFACTURING DEFENDANTS have marketed Reglan to physicians in a manner calculated to increase sales of the drug and resultant profits to the drug companies at the expense of and in conscious disregard for the health and safety of those who, through over-prescription of the drug at excessive dosage and/or for excessive periods of time and/or for patients for whom safer effective alternative treatments existed, consequently develop tardive dyskinesia and other extrapyramidal symptoms (EPS).

12.03 MANUFACTURING DEFENDANTS knew that the conditions for which metoclopramide was prescribed, in particular diabetic gastroparesis and gastroesophageal reflux, are chronic conditions which indicate, for their treatment, long-term therapy. Despite this knowledge, MANUFACTURING DEFENDANTS consciously chose to evaluate the safety and efficacy of the drug through scientific investigation for periods not exceeding 12 weeks.

12.04 MANUFACTURING DEFENDANTS knew or should have known that metoclopramide, as a dopamine antagonist and/or a neuroleptic drug, is as likely as other dopamine antagonists and/or other neuroleptic drugs to cause tardive dyskinesia and other EPS, particularly at higher exposures and longer durations of use. Despite this knowledge, MANUFACTURING DEFENDANTS consciously sponsored the performance and dissemination of non-scientific investigations to suggest that metoclopramide is safe for long-term use, proposed and distributed labeling suggesting that EPS side effects are rare with metoclopramide use, whether short-term or long-term, and otherwise systematically suppressed or undercut the dissemination of specific scientific information about the risks and prevalence of side effects associated with

Reglan®/metoclopramide to physicians, to the generic metoclopramide industry and to the FDA.

12.05 MANUFACTURING DEFENDANTS knew from their own investigations, including analysis of sales statistics, and from scientific studies published in peer-reviewed medical journals, that many physicians were unaware of the extent of the risks posed by metoclopramide therapy at high dosages and/or long-term exposure, that many physicians were over-prescribing metoclopramide, and that many patients, as a result, developed serious EPS side effects, including depression with suicidal ideation, akathisia, akinesia, tardive dyskinesia and tardive dystonia, who would not have developed these side effects but for their overexposure to Reglan®/metoclopramide. Despite this knowledge, MANUFACTURING DEFENDANTS consciously failed to make or propose any changes in the metoclopramide labeling and consciously declined to disseminate information to physicians, to the generic metoclopramide industry or to the FDA that would alert them to the fact or risk of metoclopramide exposure.

12.06 In doing the wrongful acts alleged in this Complaint, MANUFACTURING DEFENDANTS acted with oppression, fraud, and malice, evincing a willful, wanton, and conscious disregard for the rights, health, and safety of patients, including the Plaintiff, who would be expected to be induced, by that conduct, to ingest unwarranted amounts of metoclopramide for prolonged and unwarranted periods of time, leading to grievous, debilitating, and potentially permanent personal injury.

12.07 Award and assessment of punitive damages, therefore, is warranted, in an amount reasonably related to Plaintiff's actual damages and to Defendants' wealth, and sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

12.08 As a direct and proximate result of the wrongful acts of the MANUFACTURING

DEFENDANTS, Plaintiff was caused to develop severe Tardive Dyskinesia, suffered irreparable nerve damage and bodily injury, suffered and will continue to suffer great pain of body and mind, suffered and will continue to suffer great embarrassment and humiliation, suffered and will continue to suffer permanent impairment to her earnings capacity, has incurred and will continue to incur great expenses for medical treatment of her injuries, has suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

XIII.
PRAYER FOR RELIEF

13.01 **WHEREFORE,** Plaintiff respectfully requests that all issues of fact in this case be tried to a properly empaneled jury. Plaintiff further prays for relief against the Defendants, and each of them, as follows:

a. General damages as allowed by law;

b. Special damages as allowed by law;

c. Punitive damages as allowed by law

d. Costs of suit as allowed by law;

e. Attorneys' fees as allowed by law;

f. Pre-judgment and post-judgment interest as allowed by law;

g. Such further or other relief, whether legal or equitable, as the Court deems proper.

Respectfully submitted,

/s/ William B. Curtis

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CO-COUNSEL FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on January 8, 2009, I electronically transmitted the attached document to the Clerk of the Court using the ECF System for filing. Based on the records currently on file, the Clerk of Court will transmit a Notice of Electronic Filing to the following ECF registrants:

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